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Notice of Allowability	Application No.	Applicant(s)	
	10/072,660	HUANG ET AL.	
	Examiner	Art Unit	
	Alan Diamond	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment and terminal disclaimer filed November 19, 2004.
2. ☒ The allowed claim(s) is/are 1-14.
3. ☒ The drawings filed on 06 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>04/15/03, 01/30/04, 09/20/04, 11/19/04</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: Cheng et al (U.S. 6,071,394) differs from instant independent claim 1 because said claim 1 requires that the at least one capture immunoreagent specific for the bioparticles of interest are located at one or more positions of alternating field strength at which the bioparticle of interest is predicted to aggregate; and that the alternating current (AC) is maintained in step (b) for a sufficient length of time to allow the at least one capture immunoreagent to bind to the bioparticle of interest thereby immobilizing the bioparticle. In Cheng et al, cells (e.g., *E. coli* or HeLa cells), are isolated or immobilized by maintaining the AC signal at microlocations (see col. 9, lines 24-36; col. 10, line 27 through col. 11, line 19; and col. 14, lines 45-67). The streptavidin that is used by Cheng et al is not an immunoreagent for *E. coli* or HeLa cells, but rather is later used to immobilize a biotinylated probe (see col. 11, line 60 through col. 12, line 6; and col. 12, lines 50-63). In other words, after the *E. coli* cells have been isolated and removed, the streptavidin is used to immobilize the capture probe at test microlocations (see col. 11, lines 65-67). When the probe is immobilized, there are no areas of relatively high and low alternating current field strength, but rather, current is maintained on each electrode at 200 nA for one minute (see the paragraph bridging cols. 11 and 12). Furthermore, the places where the streptavidin is located are not ones of alternating current field strength where the probe is predicted to aggregate. An example of the instant method can be seen in Example 5 at pages 36-39, of the instant specification. Note in this

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example that monoclonal anti-*E. coli* capture antibody is used, and that an AC voltage of 5kHz, 5V is applied to the electrodes (see page 36, lines 21 and 31).

In step f) of instant independent claim 9, the current is maintained in step e) for a sufficient time to allow the detection immunoreagent to bind to the bioparticle of interest, from steps a) and b), at the aggregate microlocations, thereby detectably labeling the bioparticle. The bioparticle in Cheng et al would have to be the *E. coli* or HeLa cells since these are the bioparticles that are bound using the areas of relatively high and low field strength of AC, as per instant step b). However, the streptavidin of Cheng et al is not an immunoreagent for these cells. Rather, as noted above, the streptavidin is used as an "immunoreagent" for the capture probe, which is not aggregated at the microlocations using said areas of relatively high and low field strength of AC.

The provisional obviousness-type double patenting rejections over U.S. Patents 6,071,394 and 6,280,590 have been overcome by the terminal disclaimer filed November 19, 2004.

The provisional obviousness-type double patenting rejection over the claims of copending application serial No. 09/905,755 is expressly withdrawn by the Examiner since the method claims (17-20) in said copending application do not even recite an immunoreagent, let alone how an immunoreagent is used in the instant method claims. It is true that the assay system in claim 7 of said copending application recites capture probes immobilized on the permeation layer. However, this does not lead a skilled artisan to the claimed method using an immunoreagent.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

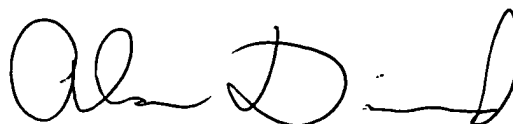
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan Diamond whose telephone number is 571-272-1338. The examiner can normally be reached on Monday through Friday, 5:30 a.m. to 2:00 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alan Diamond
January 10, 2005

Alan Diamond
Primary Examiner
Art Unit 1753

A handwritten signature in black ink, appearing to read 'Alan Diamond', written in a cursive style.